DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#24

JAN 29 1992

Re: Accupril
Docket No. 91E-0492

The Honorable Harry F. Manbeck, Jr.
Assistant Secretary of Commerce
and Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Manbeck:

This is in regard to the application for patent term extension for U.S. Patent No. 4,344,949, filed by Warner-Lambert Company, under 35 U.S.C. 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Accupril, the human drug product claimed by the patent.

The total length of the review period for Accupril is 3,441 days. Of this time, 2,414 days occurred during the testing phase and 1,027 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: June 18, 1982.

   FDA has verified the applicant's claim that the date the investigational new drug application (IND) became effective was June 18, 1982.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: January 26, 1989.

   FDA has verified the applicant's claim that the new drug application (NDA) for Accupril (NDA 19-883) was filed on January 26, 1989.

3. The date the application was approved: November 19, 1991.

   FDA has verified the applicant's claim that NDA 19-885 was approved on November 19, 1991.

This determination of the regulatory review period by FDA does not take into account the effective date of the

patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Joan Thierstein
Patent Department
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